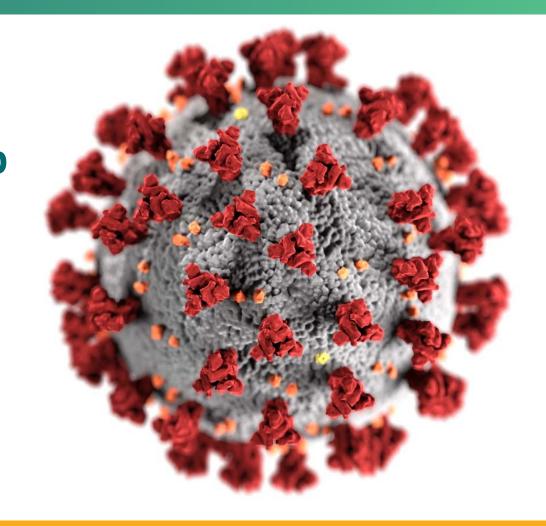
ACIP COVID-19 Vaccines Work Group

Dr. Matthew F. Daley, Work Group Chair November 2, 2021

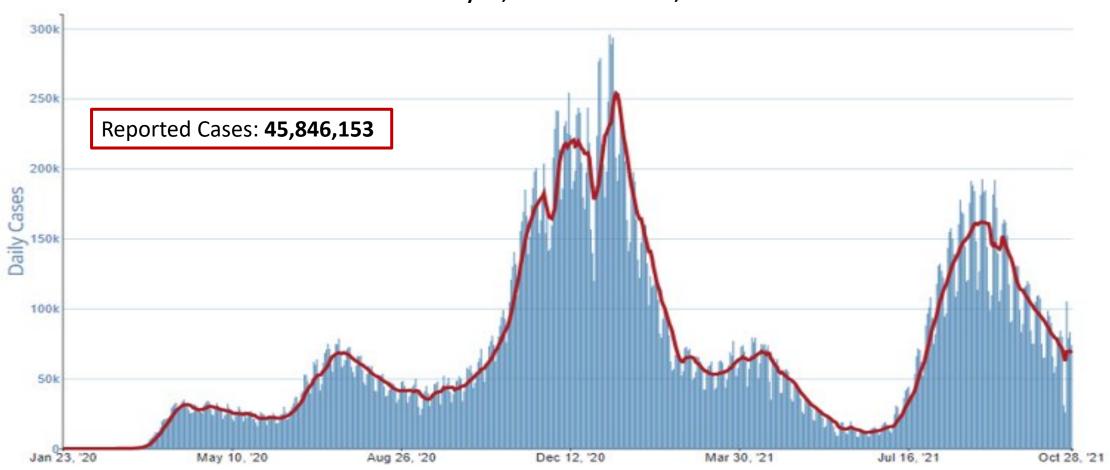




cdc.gov/coronavirus

Daily trends in number of COVID-19 cases in the United States, all ages

January 23, 2020 – October 28, 2021



Burden of COVID-19 in children 5-11 years of age

- 1.9 million cases
- 8,300 hospitalizations
- 2,316 Multisystem Inflammatory Syndrome in Children (MIS-C) cases
- 94 deaths

Burden extends beyond case counts; school interrupted, lives disrupted

COVID-19 Work Group activities – October 2021

- Reviewing data for pediatric COVID-19 vaccines
 - SARS-CoV-2 seropositivity in children
 - Pediatric COVID-19 epidemiology
 - ScenarioHub Modeling results of the impact of pediatric vaccination
 - Results of Pfizer-BioNTech clinical trial in children 5-11 years old
 - GRADEing of evidence
 - Discussion of the Evidence to Recommendations Framework

FDA expands Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to include children 5 through 11 years of age¹

Pediatric Formulation

- 10μg dose, IM
- The vaccine is administered as a 2-dose series, 3 weeks apart

Evidence:

- 5-11 year olds: 4,600 participants in a clinical trial (3,100 received vaccine, 1,538 received placebo)
- ≥12 years: >247,000,000 doses of Pfizer-BioNTech (30ug formulation) in the U.S.²
- Vaccine fully licensed in people ≥16 years old in August 2021, based on longer-term follow-up data
- 1. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine
- 2. https://covid.cdc.gov/covid-data-tracker/#vaccinations vacc-total-admin-rate-total- Accesses November 1st, 2021

Agenda: Tuesday November 1, 2021

Pfizer-BioNTech: BNT162b2 use in children aged 5-11 years

Dr. Gurtman (Pfizer)

Break

PUBLIC COMMENT

SARS-CoV-2 Epidemiology in Children

Myocarditis in adolescents and young adults

Vaccine safety surveillance in children

Implementation of COVID-19 vaccine pediatric program

Break

Clinical considerations

Evidence to Recommendations Framework

VOTE

Dr. Jones (CDC)

Dr. Oster (CDC)

Dr. Shimabukuro (CDC)

Dr. Chatham-Stevens (CDC)

Dr. Woodworth (CDC)

Dr. Oliver (CDC)

Work group members

ACIP members

- Matthew Daley (chair)
- Beth Bell
- Grace Lee
- Keipp Talbot
- Oliver Brooks

Ex-officio/government members

- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Uzo Chukwuma
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

CDC Leads

- Sara Oliver
- Kathleen Dooling

Liaisons

- AAFP: Jonathan Temte
- AAP: Sean O'Leary
- ACOG: Denise Jamieson (primary),
 Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary),
 Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary),
 Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett (primary),
 Christine Hahn (alternate)
- IDSA: Jeff Duchin (primary),
 Carol Baker (alternate)

Liaisons, cont'd

- NACCHO: Matt Zahn (primary),
 Jeff Duchin (alternate)
- NACI: Matthew Tunis
- NFID: Bill Schaffner (primary),
 Marla Dalton (alternate)
- NMA: Patricia Whitley-Williams
- SHEA: Marci Drees

Consultants

- Ed Belongia
- Kathy Kinlaw
- Dayna Matthew
- Kathleen Neuzil
- Stanley Perlman
- Peter Szilagyi
- Jose Romero
- Hank Bernstein

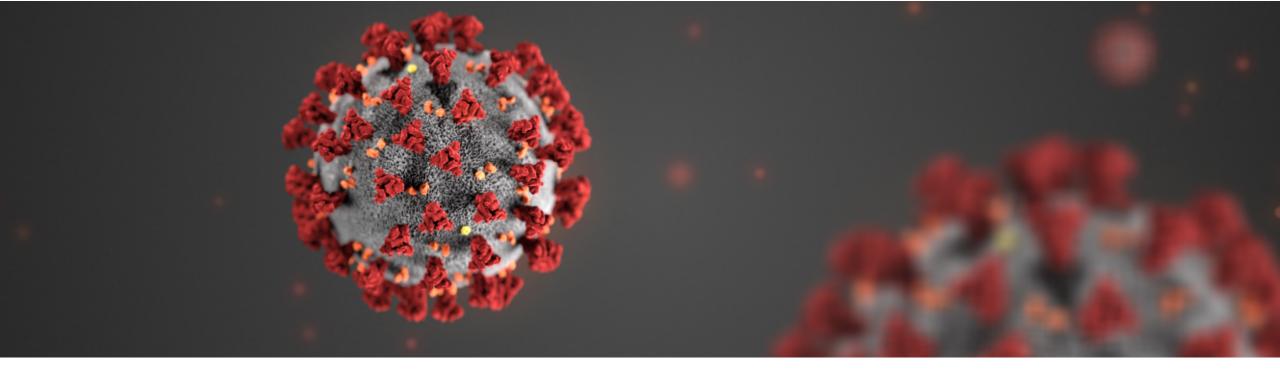
CDC participants

- Sarah Mbaeyi
- Mary Chamberland
- Amanda Cohn
- Jack Gersten
- Monica Godfrey
- Stephen Hadler
- Danielle Moulia
- Megan Wallace
- Jennifer Collins
- Sujan Reddy

- Jefferson Jones
- Edwin Shanley
- Rita Helfand
- Cynthia Jorgensen
- Megan Lindley
- Ruth Link-Gelles
- Jessica MacNeil
- Lauri Markowitz
- Jean Cox-Ganser
- Meredith McMorrow

- Rebecca Morgan
- Titilope Oduyebo
- Heather Scobie
- Edwin Shanley
- Tom Shimabukuro
- Natalie Thornburg
- Thomas Clark
- Doug Campos-Outcalt
- Jillian Doss-Walker
- Andrew Kroger

- Melinda Wharton
- Kate Woodworth
- Yon Yu
- Kristin Nordland
- Kevin Chatham-Stevens
- Erin Tromble
- Dana Meaney-Delman
- Thomas Clark
- Sam Graitcer
- Lisa Grohskopf



For more information, contact CDC 1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

